NRC INSPECTION MANUAL

NMSS/MSIB

INSPECTION PROCEDURE 87112

IRRADIATOR PROGRAMS

PROGRAM APPLICABILITY: 2800

87112-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements.

While this inspection procedure can be used for construction inspections, Manual Chapter 2815, "Construction and Preoperational Inspection of Panoramic, Wet-Source-Storage Gamma Irradiators," is also available for that type of irradiator.

87112-02 INSPECTION REQUIREMENTS

A review of the licensed activities will be commensurate with the scope of the licensee's program. A determination regarding safety and compliance with NRC requirements will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspections. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

Some of the following areas may not be applicable to all irradiator licensees. In particular, many of the following elements and requirements will not be applicable to self-contained dry-source-storage irradiator licensees. Also, references to 10 CFR 36 requirements only apply to irradiators for which the dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources.

02.01 <u>Preparation</u>. The inspector should allow adequate time to prepare for the inspection. Preparation will include reviewing documents, making travel arrangements, coordinating with appropriate staff, notifying appropriate State agencies, and selecting necessary equipment. In particular, the inspector shall identify whether any license amendments have been issued since the last inspection, or whether the licensee has informed NRC of any major program changes since the last inspection. The inspector shall

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also review the Nuclear Materials Events Database (NMED) and any regional event logs and files to determine if the licensee had any incidents or events since the last inspection.

02.02 <u>Entrance Briefing</u>. When the inspector arrives at the licensee's facility, he/she will inform an available senior management representative of the purpose and scope of the inspection.

02.03 General Overview

- a. <u>Organization</u>. Interview cognizant licensee representatives about the current organization of the program. Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Identify the reporting relationship and management structure between the licensee's executive management and the Radiation Safety Officer (RSO).
- b. <u>Scope of Program</u>. Interview cognizant personnel to determine the types, quantities, and use of byproduct material, frequency of use, staff size, etc.
- c. <u>Management Oversight</u>. In the course of interviewing cognizant personnel, determine if management oversight is sufficient to provide the licensee staff with adequate resources and authority to administer the licensed program.
 - RSO Determine whether the RSO has been appointed and is named on the license, has sufficient authority, in particular to stop unsafe operations, and fulfills the appropriate duties commensurate with the size and scope of licensed activities. Note that if the RSO does not have authority to stop unsafe operations, someone else within the management structure, named in the license application, must.
 - 2. <u>Audits</u> Verify that audits are performed as required. Verify that the results of the audits are reviewed and addressed.
 - 3. <u>Staff resources</u> Verify that the staffing levels are adequate to support the licensee's program, including continuous operation of the irradiator using multiple shifts, if applicable, and that the licensee's management reviews the resource needs on an ongoing basis.
- d. <u>Authorized Operators</u>. Determine that only authorized individuals perform and/or supervise licensed activities. Verify that the irradiator operators are qualified and have successfully completed the training and testing described in 10 CFR 36.51. Also verify that authorized users perform an appropriate level of supervision, as required by the license or regulations.
- 02.04 <u>Walk-Through Orientation Tour</u>. Perform a walk-through tour of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed.
- 02.05 <u>Facilities</u>. Verify that the facility conforms to that described in the license application; that material receipt, use, and storage areas are secured; and that the licensee uses processes or other engineering controls to maintain doses as low as is reasonably achievable (ALARA).
 - a. Verify that the requirements of 10 CFR 36.23 for control of access to the radiation room are met. A demonstration of the checks performed on the access controls is an appropriate verification.

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- b. Verify that the shielding meets the requirements of 10 CFR 36.25. Several independent measurements to confirm the licensee's survey data are acceptable verifications. Special emphasis should be given to areas where ducting or wireways pass through shielding, edges of walls and doors where shielding overlaps, and where visible defects/cracks appear in the walls.
- c. Verify that the fire protection requirements of 10 CFR 36.27 are met. Discussions with the operators regarding the systems and procedures in the event of fire, and observations of the detectors, alarms, and fire extinguishing systems are acceptable verifications.
- d. The inspector should verify that the mechanisms to control source movement meet each of the requirements of 10 CFR 36.31.
- e. Verify that sealed sources installed after July 1, 1993, meet the performance criteria of 10 CFR 36.21. This may be performed by a review of the sealed source registration certificate.
- f. Verify that irradiator pools initially licensed after July 1, 1993, meet the requirements of 10 CFR 36.33. Visual observation of the pool is acceptable verification.
- g. If the product moves on a conveyor system, verify that the source rack and movement mechanism are protected by a barrier or guide, as required by 10 CFR 36.35.
- h. Verify that the facility complies with the design requirements of 10 CFR 36.39 and that the licensee performed the pre-source-loading construction monitoring and acceptance testing requirements of 10 CFR 36.41. These verifications involve reviewing the licensee's records on the required design checks, construction monitoring, and acceptance testing.
- i. Verify that any self-contained dry-source-storage irradiator use complies with the requirements in 10 CFR Part 20 and applicable license conditions.
- j. Examine the licensee's evaluation or documentation to demonstrate compliance with dose limits for individual members of the public. [10 CFR 20.1302]

02.06 Equipment and Instrumentation

- a. Verify that equipment and instrumentation are appropriate, operable, calibrated, adequately maintained, and conform to those described in the license. Personnel monitoring devices must be accredited and processed in accordance with 10 CFR 36.55. Survey instruments must be calibrated in accordance with 10 CFR 36.57.
- b. Verify that the licensee has established and implemented procedures to identify and report safety component defects per the requirements of 10 CFR Part 21.
- c. Verify that the licensee has established procedures to perform the inspection and maintenance requirements of 10 CFR 36.61. Verify that non-routine operations (e.g. repairs) are performed by authorized personnel (licensee or others). Procedures and their implementation (practices) must be consistent with license commitments.

02.07 Materials

a. Receipt and Transfer of Licensed Material. Verify that the licensee is receiving packages and making transfers of licensed material in accordance with NRC and

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- applicable U.S. Department of Transportation (DOT) regulations and license conditions.
- b. <u>Authorized Uses</u>. Determine from observing the use of licensed material, discussing the activities with licensee personnel, and reviewing records, that the type, quantity, and use of licensed material at the licensee's facility are authorized by the license. To the extent practical, ensure by physical confirmation that the licensee's inventory is complete and accurate.
- c. <u>Material Security and Control</u>. Verify that the licensee has established procedures for maintaining security and control of licensed material, and that these procedures are understood and implemented by appropriate personnel.
- d. <u>Loading, Unloading, and Repositioning of Sources</u>. Verify that loading, unloading, and repositioning the sources are performed by either the licensee or an organization specifically authorized by the Commission or an Agreement State to perform these operations, per the requirements in 10 CFR 36.13(g). If the licensee performs these operations, the procedures used must be authorized in the license.

02.08 Training

- a. <u>General Training</u>. Verify that appropriate training and initial instructions are being accomplished as specified in the license and/or regulations.
- b. Operating and Emergency Procedures. Verify that operational procedures are being followed by observing licensee personnel perform tasks at selected work stations and by a comparison of their activities with established procedures. Also examine the licensee's emergency procedures to determine that these procedures are as approved by NRC. Through discussions with workers, verify that licensee personnel understand and implement the established procedures and are aware of procedural revisions. Document in the inspection field notes what activities the inspector observed.

When applicable, discuss with the licensee's representatives, or observe, the conduct of periodic tests and drills, especially for scenarios involving fires and large releases of radioactive material.

c. <u>Operator Training</u>. Verify that the irradiator operator training program developed and implemented by the licensee meets the requirements of 10 CFR 36.51.

02.09 Area Radiation and Contamination Control

- a. <u>Area Surveys</u>. Verify, during observations and by direct measurements, that the radiation levels are within the limits of Part 20 and 10 CFR 36.25, and that these areas are properly posted.
- b. <u>Leak Tests</u>. Verify that tests for leaking sources are performed in accordance with the manufacturer's recommendations, the requirements of 10 CFR 36.59, and/or the license. Also, verify that the leak test is analyzed in accordance with the license. If records of leak test results show contamination in excess of the regulatory requirements, verify that the licensee made appropriate notifications and removed the source from service.

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02.10 Radiation Protection

- a. <u>Radiation Protection Program</u>. Verify that a radiation protection program commensurate with the licensee's activities is being implemented and documented, and that the program is being reviewed at least annually, both for content and implementation.
- b. <u>Radiation Protection Procedures</u>. Verify that changes in the radiological protection procedures made since the last inspection are consistent with regulations and license requirements. [Note that some procedures may require prior NRC approval before the licensee can make changes.]
- c. <u>Instruments and Equipment</u>. Verify that radiation protection instruments and equipment are operable; have the proper alarm settings (if applicable); and are calibrated and checked for appropriate response in accordance with 10 CFR 36.55(b) and 36.57(c) and licensee procedures.
- d. <u>Personnel Dosimeters</u>. Verify that personnel dosimetry devices are worn by appropriate licensee personnel in accordance with 10 CFR 36.55. Dosimetry devices appropriate to the type, energy or emitted radiation, and the anticipated radiation fields should have been issued to facility personnel. Verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program -approved and -accredited processor.

Verify that, pursuant to 10 CFR 19.13(b), the licensee advises each worker annually of the worker's dose, as shown in records maintained by the licensee pursuant to the provisions of 10 CFR 20.2106, "Records of individual monitoring results."

02.11 Waste Management

a. <u>Effluents</u>. Review and verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within the limits established by the license, 10 CFR 36.57(d) and (e), and other regulatory requirements, and are ALARA.

Determine the quality of the relevant procedures and the degree to which ALARA techniques are incorporated into them. Determine the extent to which process and engineering controls are used to minimize effluents.

Determine whether effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with manufacturer's recommendations and good health physics practices.

Determine if all significant release pathways are monitored, all un-monitored pathways have been characterized, and all surveillance procedures for effluents are being implemented.

Additional inspection requirements are specified in Inspection Procedure (IP) 87102, "Maintaining Effluents from Materials Facilities as Low as Is Reasonably Achievable (ALARA)."

b. <u>Transfer</u>. Verify that licensed materials are transferred to an authorized recipient specifically licensed to receive it, in accordance with 10 CFR 30.41.

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- c. <u>Records</u>. Verify that records of waste storage, transfer, and disposal are maintained in accordance with the requirements of Part 20, 10 CFR 36.81(k), and the license.
- d. <u>Financial Assurance and Decommissioning</u>. For all licensees, including sealed source licensees, review the licensee's records of information important to the safe and effective decommissioning of the facility. Verify that the records are complete, updated, and assembled appropriately, in accordance with the requirements in 10 CFR 30.35(g). Review the licensee's list of restricted areas required under 10 CFR 30.35(g)(3) and determine whether rooms have been released since the last inspection. If areas have been released, verify that the licensee has adequately decontaminated each room and documented the basis for releasing each room. Document the location of the released rooms in the field notes, and document your findings regarding the adequacy of the licensee's decontamination.

Verify whether radiological conditions at the facility have changed since the financial assurance instrument and/or decommissioning plan was submitted such that either document needs to be changed to address the new radiological conditions. Examples of changes are radiological incidents such as spills or process upsets. Unauthorized changes by the licensee to processes, types of licensed materials, possession limits, or chemical or physical forms of licensed materials may also prompt a reevaluation of whether the financial assurance instrument and/or decommissioning plan remains sufficient. If the inspector identifies changes that may affect the financial assurance instrument or decommissioning plan, he/she should immediately notify regional management.

If a parent company guarantee or a self-guarantee is used to ensure decommissioning financial assurance, review the licensee's financial assurance file to ensure that 10 CFR Part 30, Appendix A or Appendix C requirements are met.

- e. <u>Decommissioning Timeliness</u>. Review compliance with the Decommissioning Timeliness Rule requirements in 10 CFR 30.36(d) through (h). This is one area of the field notes that should be completed on all inspections. If the license to conduct principal activities has expired or been revoked; if the licensee has made a decision to permanently cease principal activities at the site, in any separate building, or at any outdoor area; or if there has been a 24-month duration when no principal activities were conducted at the site, in any separate building, or at any outdoor area, then the decommissioning timeliness requirements in 10 CFR 30.36, 40.42, 70.38, or Part 72 apply. If this is the case, the inspector must complete in full the "Decommissioning Timeliness Inspection Attachment," Attachment A to Appendix A.
- 02.12 <u>Transportation</u>. Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is transported in accordance with 10 CFR Part 71 and U.S. Department of Transportation (DOT) regulations for transportation of radioactive materials.
- 02.13 <u>Posting and Labeling</u>. Verify that the licensee has posted the appropriate documents, notices, forms, and caution signs, as required. Also verify that containers of licensed material are labeled appropriately.
- 02.14 <u>Generic Communications of Information</u>. Confirm that the licensee is receiving the applicable bulletins, information notices, <u>NMSS Licensee Newsletter</u>, etc. Verify that the licensee has taken appropriate action in response to these notices.
- 02.15 <u>Notifications and Reports</u>. Determine compliance with the regulations and license requirements for notification and reports to NRC.

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- 02.16 <u>Special License Conditions</u>. If applicable, review the licensee's compliance with any special license conditions.
- 02.17 <u>Independent and Confirmatory Measurements</u>. Compare and verify on a sampling basis, survey results or data that are used by the licensee to show compliance with the regulations or license conditions. Conduct independent measurements to ascertain the radiological conditions of the facility. Conduct these independent measurements on all inspections under this IP, unless warranted by special circumstances. If independent measurements were not made, provide a justification in the field notes explaining why independent measurements were not performed. The inspector shall use radiation detection instruments that are calibrated at least annually.
- 02.18 <u>Exit Meeting</u>. The inspector will conduct an exit meeting with senior licensee management and the RSO to discuss the preliminary inspection findings, including any apparent violations, safety-related concerns, and any unresolved items identified during the inspection. Discuss any negative performance evaluation factors (PEFs) and encourage the licensee to respond to the PEFs of concern. For further guidance, refer to IP 87107, "Performance Evaluation Factors."
- 02.19 <u>Post-Inspection Actions</u>. After an inspection, the inspector shall summarize the findings with his/her appropriate NRC supervisor. This is especially important if there are, or are expected to be, controversial issues arising from the findings.

Inspectors shall also meet with regional licensing staff when any pertinent licensing issues are raised during the inspection, when inspection findings impact on any licensing actions, to discuss the licensee's PEF results, or to give feedback on how the licensee has addressed recent licensing actions. This meeting shall be documented in the field notes.

Additionally, in some instances, inspection findings will warrant communication with enforcement staff, Office of Investigations staff, State liaison staff, or Federal agencies with whom NRC has Memoranda of Understanding (MOUs).

The inspector will ensure that inspection findings are clearly documented, and reported to the licensee as appropriate. The inspector shall also follow the requirements of Inspection Manual Chapter (IMC) 0620, "Inspection Documents and Records," regarding notifying the licensee that retained information is subject to public disclosure and giving the licensee the opportunity to request withholding it (see IMC 0620, Section 04.06.b.).

87112-03 INSPECTION GUIDANCE

General Guidance

An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, observations of activities in progress, equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records alone.

Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, observations, and demonstrations.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent release, receipt and transfer of radioactive materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-

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monitoring records and incident reports) should be examined in detail. The type of records that were reviewed and the time periods covered by these records should be noted in the appropriate "Basis for Findings" section(s) of the inspection field notes.

Retain a copy of each pertinent record that is needed to substantiate an inspection finding, such as a violation. Those copies shall be attached to the inspection field notes or, when applicable, to a written inspection report. When an inspector identifies an apparent violation, he/she should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations; expedite the inspection (e.g., licensee materials inventories); or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, follow the requirements of IMC 0620. Especially ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information pursuant to the requirements of 10 CFR 2.790(b)(1).

The inspector should keep the licensee apprised of the inspection findings throughout the course of the inspection and not wait until the exit meeting.

Whenever possible the inspector should keep NRC management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection.

Specific Guidance

- 03.01 Preparation. Before the inspection, the inspector should do the following:
 - ! Review the licensee's previous inspection history (at a minimum, review the past two inspections); the license; and the status of any allegations or incidents. Note the licensee's commitments in response to previous violations, for followup during the inspection;
 - ! Review the Nuclear Materials Events Database (NMED) and regional event/incident logs, event/incident files, and the docket file to determine whether the licensee was involved in any incidents or events. If NRC did receive notification of an incident, review that incident during the inspection and document the licensee's followup in the inspection record;
 - ! In the inspection record, complete the administrative information, the inspection compliance history, the listing of any license amendments or program changes since the last inspection, and the description of any incidents or events that have occurred since the last inspection;
 - ! Determine the dates that the licensee submitted the most recent financial assurance instrument and decommissioning plan (if applicable);
 - ! Discuss the licensee's program with previous inspector(s) and/or license reviewer(s) as necessary;
 - ! Notify the appropriate State radiation control program personnel;
 - ! Review pending licensing actions;
 - ! Obtain a map of the area and/or directions;
 - ! Make travel arrangements and prepare itinerary;

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- ! Select calibrated instruments and perform source check;
- ! Select appropriate documents; and
- ! Select appropriate equipment to take.

In selecting the appropriate documents, the inspector should consider taking the applicable regulations, inspection record, generic communications, license, NRC forms, etc.

In selecting the appropriate equipment the inspector should consider the type of licensee to be inspected. The equipment may include safety glasses and safety shoes, sample vials, wipes, pocket dosimeters, alarming rate meters, etc.

During the inspection, focus (among other areas) on whether the licensee is in compliance with any license amendments issued since the last inspection or with any program changes described by the licensee since the last inspection. This requires review of documentation submitted in support of the licensing action, before the inspection. The inspection represents NRC's first opportunity to verify whether the licensee has enacted the most recent changes to the license.

03.02 <u>Entrance Briefing</u>. After arriving on site, the inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This notification should be made as soon as practical after arriving on site. However, in certain instances the inspector may choose to inform the licensee of his/her presence on site after initial observations of licensed activities currently in progress.

The purpose of the entrance briefing is to inform licensee management that an inspection is being conducted, and to indicate the tentative schedule for discussing or reviewing selected inspection items with various licensee staff personnel. However, in some instances, the inspector may only need to inform management of NRC's presence on site, and apprise management that an exit briefing will be conducted, at the end of the inspection, which will detail the inspection findings.

This is often an opportune time for the inspector to identify personnel to be interviewed. Scheduling interviews will enhance inspector efficiency and give the licensee the opportunity to have the most knowledgeable individuals present to respond in the areas being inspected.

Certain inspection items involving visual observations and/or records review are better performed unannounced; therefore, these types of items should not be discussed during the entrance briefing.

03.03 <u>General Overview</u>. The inspector will interview the cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. <u>Organization</u>. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. Determine the reporting structure between executive management and the RSO. Determine whether the RSO has sufficient access to licensee management. Through discussions with licensee staff, the inspector should determine if changes in control or staffing have occurred. If the owner or individuals named in the license have changed, determine whether the licensee has submitted appropriate notification to NRC. This information must be provided whenever changes in control or personnel are made (except for some licenses where only responsibilities are defined). Ask licensee management if changes have occurred, or are anticipated, and ask personnel to confirm (to the inspector's satisfaction) that no changes have

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taken place. If there have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail.

The inspector should review any organizational change in the RSO position, authorities, responsibilities and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should ask licensee management and the RSO about the RSO's authority and about any changes that may impact on the RSO's duties, responsibilities, or effectiveness.

- b. <u>Scope of Program</u>. Through discussions with licensee personnel, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc., that cannot always be gained by reviewing records alone. This is also an opportunity for the inspector to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection.
- c. <u>Management Oversight</u>. The inspection is a verification of the licensee's implementation of the required program. In the review to verify implementation, the inspector should pay particular attention to the scope of the program; the adequacy of the staffing levels to support the program; frequency of licensee audits and the use of qualified auditors; procedures for recording and reporting deficiencies to management; and methods and completion of followup actions by management.
 - 1. RSO The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program. The inspector should verify that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify that, when deficiencies are identified, the RSO has sufficient authority to implement corrective actions, including termination of operations that pose a threat to health and safety. Note that if the RSO does not have authority to stop unsafe operations, someone else within the management structure, named in the license application, must.
 - 2. Audits The frequency and scope of audits of the licensed program will vary. However, note that at a minimum, licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. Additionally, irradiator licensees are required, by 10 CFR 36.51, to perform annual reviews for irradiator operators and evaluate the safety performance of each irradiator operator. The results of audits should be documented. Examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.
 - 3. <u>Staff resources</u> The scope of a licensee's program may necessitate continuous operation of the irradiator over multiple work shifts. The irradiator utilization log should be examined and compared with information on staff resources (e.g., number of irradiator operators) to determine whether the staffing level is commensurate with safe operation of the irradiator over all shifts. Through discussions with the licensee's staff and/or management, the inspector should determine if management periodically reviews the staff resources required to support the licensee's current program.

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d. <u>Authorized Operators</u>. Authorized operators may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify that authorized operators are trained in accordance with the approved criteria and have knowledge commensurate with operational duties.

Determine that the authorized operators are personally performing or, if permitted in the license, supervising the authorized work, rather than someone else not named in the license. Non-authorized operators may only operate the irradiator in the presence of a supervisor who is an experienced authorized user.

03.04 <u>Walk-Through Orientation Tour</u>. The inspector should make initial observations of licensed activities to determine that materials are being safely handled/used and that good health physics practices are followed. The inspector should look at areas of use, storage, and transfer to make an initial assessment of the licensee's ALARA program with regard to facility design, engineering controls, house-keeping practices, etc. The inspector should ensure that observations of activities are documented in the inspection record.

03.05 <u>Facilities</u>. Descriptions of the facilities are generally found in the applications for a license and subsequent amendments that are usually tied down to a license condition. The actual or as-built facility should be configured to provide safe working areas separated from unrestricted areas and sufficient access controls to preclude unauthorized entry. The inspector should also be aware of potential industrial safety hazards, as well as the potential health hazard of ozone within the radiation facility, for referral of concerns to the U.S. Department of Labor's Occupational Safety and Health Administration. [Note that irradiators with large sources are typically equipped with ventilation systems to exhaust ozone (and nitrogen oxides), produced by irradiation of air. Such facilities could be expected to also have operative ozone monitors as well as procedures to restrict access of personnel to areas when ozone concentrations exceed OSHA limits. Also, note that ozone can be detected by odor at a concentration which is 15% of the OSHA concentration limit; ozone odor does not necessarily indicate that an air concentration of ozone warranting concern is present.]

In addition, irradiator facilities have multiple design and performance requirements, found in Subpart C of 10 CFR Part 36, that are mandatory. Although many of these requirements, such as those involving the sealed sources and those involving pre-source-loading construction monitoring and acceptance testing, can only be verified by reviewing records, other requirements, such as those found in 10 CFR 36.23 for access control, should be licensee verified by demonstration by the licensee (e.g., by performance of interlock checks).

Some irradiator licensees, in particular those using converted teletherapy units, have received exemptions from some of the safety systems described in Subpart C of Part 36. Usually these exemptions are granted based on administrative procedures committed to by the licensee. Inspectors should check the license to ensure that the administrative commitments on which these exemptions were granted are actually implemented by the licensee and are effective.

03.06 Equipment and Instrumentation

a. Equipment and instrumentation should be appropriate to the scope of the licensed program. The inspector should verify that survey instrumentation has the appropriate range of use, which for some licensees can be found in the regulations. The inspector should also verify that the survey instruments are calibrated at least annually and in accordance with the requirements in 10 CFR 36.57(c). All survey, sampling, and monitoring instruments should have current calibrations appropriate to the types and energies of radiation to be detected. The technical adequacy of

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calibration procedures at facilities that perform their own calibrations should be examined. Processing equipment, ventilation, and exhaust systems should be sufficient to provide safe use, handling, and storage of the materials in use. An operable, calibrated, conductivity meter should be available.

- b. Inspectors should verify that licensees have procedures for reporting defects in accordance with Part 21. The complexity of the procedures will vary. Manufacturers should have detailed procedures to evaluate the safety significance of identified defects. Other licensees need only address identification and reporting requirements.
- c. Inspectors should verify that the licensee has procedures to perform the inspection and maintenance requirements of 10 CFR 36.61. The licensee should have a procedures manual for performing the inspections, as well as a log book, of the outcomes of the inspections, that can be reviewed. Procedures, as well as practices (as determined by review of records and interviews of staff), for maintenance, repair, modification, or replacement of equipment affecting safe operation of the facility must be consistent with licensee commitments regarding what will be done by licensee personnel (and the training to be provided for such activities) and what functions will be conducted by outside personnel (equipment manufacturers or others).
- d. Verify that equipment and procedures comply with the requirements in 10 CFR 36.23, 36.31, and 36.37.

03.07 Materials

a. Receipt and Transfer of Licensed Materials. Depending on the size of the licensed program, the package receipt and transfer procedures (a few or many) will be found in the license application. These procedures should be carefully reviewed before an inspection is conducted. By discussions with the licensee, determine if the procedures have been changed or modified. Some changes will require a license amendment, whereas other minor changes (updating telephone numbers, editing procedures for clarity, etc.) may not require NRC approval. Randomly examine procedures used by the licensee to determine if they are in accordance with those identified in the license application, and determine whether these changes warrant a license amendment.

The procedures for picking up, receiving, and opening packages should include how and when packages will be picked up, radiation surveys and wipe tests of packages to be done on receipt, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). The procedures also should include what actions are to be taken if surveys reveal packages that are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should, when practical, observe personnel perform the package receipt surveys.

The inspector should randomly examine records of package surveys and also determine if inventories for each radionuclide are within the license limits. In this regard, records of inventories after receipt and transfer should indicate/demonstrate that the materials on hand at any one time are within the licensee's possession limit. When practical, the records examined should be compared with a physical inventory of materials possessed.

The licensee should have an accounting system that suits the type of licensed program. For example, a beam-type facility will generally need to maintain receipt

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records, disposal records, and records of any transfers of material. However, a facility with a pool irradiator with multiple sources will need a sophisticated accounting system, for all licensed material, that provides accurate information on the receipt, location, the quantity used and disposed of, and the amount transferred to other laboratories operating under the same license. In both types of accounting systems, the licensee should perform routine physical audits to ensure the accuracy of the system.

- b. <u>Authorized Uses</u>. Authorized uses of byproduct material will be found in the licenses. Licenses will list the isotopes, physical or chemical forms, and the maximum possession limits. Note that irradiation of explosive material is prohibited (unless authorized in writing by the Commission) and that irradiation of more than small quantities of flammable material is prohibited in panoramic irradiators (unless authorized in writing by the Commission). The inspector should physically examine the inventory of radioactive material on hand (e.g., check for any sources that may have fallen off the source rack) or examine the records of receipt and transfer, to determine that quantities and forms are as authorized. Additionally, the inspector should verify that the licensee's use of byproduct material is limited to that which is authorized in the license.
- c. <u>Material Security and Control</u>. Examine areas where licensed materials are used and stored. Storage areas should be locked and have limited and controlled access. Licensed material use areas should be under constant surveillance or physically secured. The licensee should have procedures for access controls. Controls may include a utilization log to indicate when radioactive material is taken from and returned to storage areas. The inspector should verify that adequate controls are in place and working effectively.
- d. <u>Loading, Unloading, and Repositioning Sources</u>. If the licensee loads, unloads, or repositions sources, interview personnel who are authorized to perform the operations, to determine that contamination surveys of the shipping cask, radiation monitoring during operations, and (not a 10 CFR Part 36 requirement) recording of the location of each individual source placed in the source rack are performed. Review the survey records to confirm that the surveys were performed.

03.08 Training

a. General Training. Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application). The instruction, testing, training, periodic safety reviews and safety performance evaluations required for individuals operating an irradiator without a supervisor present are listed in 10 CFR 36.51. Also listed in that section are training requirements for individuals permitted unescorted access to irradiators and for individuals who must be prepared to respond to alarms.

Verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements. Also verify that

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authorized users and workers understand the mechanism for raising safety concerns.

Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. One or more users of radioactive materials should be interviewed to determine that they have received the required training, both in the basic instructions and that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to a worker before the individual's performance of licensed activities.

Randomly examine records of training of personnel and attendant examinations or tests (if applicable) to the extent that the inspector is satisfied that the training program is being implemented as required. Where examinations are required, read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out his/her responsibilities.

The inspector should also observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. An example of an activity to observe is entering and leaving the radiation room, with requirements of this activity listed in 10 CFR 36.67. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

b. Operating and Emergency Procedures. Operating and emergency/abnormal event procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for lower inspection-priority licenses. The emergency procedures will be approved by NRC and reviewed and updated by the licensee. The licensee can revise these procedures, without Commission approval, if the conditions of 10 CFR 36.53(c) are met. The inspector should verify that the conditions were met for any revisions of these procedures made without NRC approval.

Some licensees may have agreements with other agencies (i.e., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

c. Operator Training. The inspector should review examples of tests and scoring to determine that knowledge of the relevant topics of 10 CFR 36.51 are effectively covered in the training program. The inspector should interview the licensee's training coordinator to ascertain the licensee's method of reinstructing and retesting those operators who do not initially pass the testing. Specifically check the licensee meeting the 10 CFR 36.51(d) and 36.51(e) requirements for operator safety reviews and safety performance evaluations being conducted at least annually.

03.09 Area Radiation and Contamination Control

a. <u>Area Survey</u>. The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation. However, the inspector

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must use NRC's instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated within the frequency required for the licensee and source-checked before he/she leaves the regional office.)

If practical, observe how licensees conduct surveys, to determine the adequacy of surveys. Also, note the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured. The survey activities should be at a specified frequency in accordance with the related licensee procedures. The inspector should also perform independent measurements, as needed, to verify licensee assumptions or measurements.

- b. <u>Leak Tests</u>. Through discussions with licensee personnel and/or by demonstration of leak-test procedures, the inspector should verify that leak tests are performed in accordance with 10 CFR 36.59 and/or license requirements. Also verify that records are maintained in accordance with 10 CFR 36.81.
- c. <u>Contamination Control</u>. Generally, contamination control will not be a concern for irradiator licensees unless the sources have leaked. The inspector should verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination, in accordance with 10 CFR 36.59(c). The inspector may choose to examine the instrument calibration records (efficiency checks, lower-limit-of-detection calculations, etc.); physical location of counting instruments; methods of detection; and pool-water-sample locations. Additionally, when appropriate, the inspector should consider taking confirmatory pool-water samples.
- d. <u>Pool irradiators</u>. Ensure that the licensee performs the following: 1) cleanup and cooling system operated as required by license; 2) demineralizers are operated and maintained in accordance with license conditions; 3) pool-water level and quality are maintained in accordance with license conditions; and 4) radiation monitor activates alarm [10 CFR 36.59(b)].
- e. <u>Licensee Checks</u>. Ensure that the licensee performs the following: 1) checks that access controls are operational; 2) checks that radiation monitors are operational; 3) checks that operators and product handlers are present during operation and trained as required by 10 CFR 36.51(f) and (g); and 4) checks that room-entry procedures are observed by licensee personnel.

03.10 <u>Radiation Protection</u>. Specific guidance is set forth in IP 83822, "Radiation Protection."

Part 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose as shown in dose records maintained by the licensee. Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

Inventories should be performed in accordance with license condition. In conducting inventories, licensee should know condition (serial number and activity) of all sources.

Shield surveys should be completed before initial operation, after source exchange or modification, and at intervals not to exceed 3 years [10 CFR 36.57(a)]. Verify that dose rates conform to the requirements specified in 10 CFR 36.25(a) and (b).

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Verify that the licensee has established a product-monitoring program in accordance with license conditions and 10 CFR 36.29.

03.11 Waste Management

a. <u>Effluents</u>. Examine the waste release records generated since the last inspection, all annual or semiannual reports, all pertinent non-routine event reports, and a random selection of liquid effluent release records. Randomly select procedures for liquid effluent releases and verify that the licensee's procedures are being followed. The verification can be made by observations of an operation, a review of selected records, interviews with workers, etc.

Review the licensee's ALARA goals, and determine if they are sufficiently challenging, yet realistic. Determine if the licensee understands and implements these goals. Review the licensee's history in meeting ALARA goals, and its corrective actions, when the goals were not met.

- b. <u>Transfer</u>. Ascertain if the licensee has an adequate method of determining that recipients of radioactive wastes are licensed to receive such waste (i.e., licensee obtains a copy of the waste recipient's current license, before the transfer).
- c. <u>Records</u>. Because of the nature of the licensed materials possessed by an irradiator licensee, disposals through land burial are unlikely, unless decontamination activities were necessary to deal with a leaking source. Determine if the licensee has applied for license amendments for land burial of any leaking sources.

Each licensee is required to maintain records of the disposal of licensed material made under 10 CFR 20.2002-2005 and disposal by burial in soil. These records must be retained until the Commission terminates each pertinent license requiring the record. The inspector should review these records to verify that disposals are made in accordance with the applicable regulations, and that records are complete and accurate for each type of disposal.

<u>Financial Assurance and Decommissioning</u>. The decommissioning record-keeping d. requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: (1) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site (when contamination remains after cleanup, or when contaminates may have spread to inaccessible areas, such as seepage into concrete); (2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination (e.g., buried pipes), or appropriate records of available information if drawings are not available,; (3) except for areas with only non-leaking sealed sources or byproduct materials with half-lives of less than 65 days, a single document detailing restricted areas and formerly restricted areas, buried waste, areas requiring decontamination that are outside of restricted areas, and areas outside of restricted areas that, if the license expired, would have to be decontaminated or approved for disposal; and (4) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). On all inspections, including inspections of sealed source licensees, the inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

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Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside the reporting requirements in the "Decommissioning Timeliness Rule," if the licensee continues to conduct other activities in the same building. Inspectors should identify the rooms that have been released since the last inspection and perform confirmatory measurements to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records.

Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify NRC. The inspector should be aware of changes in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to NRC. Then during the inspection, through observations, discussions with licensee personnel, and records review, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to NRC. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should immediately contact regional management from the licensee's site to discuss the situation.

Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent- company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a certified public accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendices A and C, respectively, to Part 30.

e. <u>Decommissioning Timeliness</u>. Determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, determine if the licensee has made a decision to cease principal activities at the site or in any separate building or outdoor area, including burial grounds. Finally, determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one that is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply, and the inspector must complete in full the "Decommissioning Timeliness Inspection Attachment," Attachment A to Appendix A.

The requirements of 10 CFR 30.36, 40.42, and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. However, in those cases, the inspector should follow the guidance in the above 03.11.d., regarding confirmatory measurements of the released area. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

"The Decommissioning Timeliness Rule," became effective on August 15, 1994. In completing the Attachment A inspection record, specific guidance is needed regarding the timing of the notification requirements. If the license has expired or

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been revoked, or if the licensee has made a decision to permanently cease principal activities, and the licensee provided NRC notification before August 15, 1994, then August 15, 1994, is considered to be the date for initiating the decommissioning calendar (i.e., date of notification). If there has been a 24-month duration in which no principal activities have been conducted at the location before the effective date of the rule, but the licensee did not notify NRC, then the 24-month time period of inactivity is considered to be initiated on August 15, 1994, and the licensee must provide notification to NRC within either 30 or 60 days of August 15, 1996 (depending on whether the licensee requests a delay).

NRC has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the "Decommissioning Timeliness Rule," (failure to notify NRC, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may be classified as a Severity Level III violation and may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

Decommissioning timeliness issues can be complex. For situations where an inspector has questions about the licensee's status and whether the decommissioning timeliness standards apply, he/she should immediately contact regional management.

For planning and conducting inspections of licensees undergoing decommissioning, refer to IMC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and the draft Decommissioning Manual Chapter and Handbook.

03.12 <u>Transportation.</u> The inspector should review: the licensee's hazardous material training; packages and associated documentation; vehicles (including placarding, cargo blocking, and bracing, etc.); shipping papers; and any incidents reported to DOT. NRC and DOT regulations for transportation of radioactive materials were recently revised, and the revisions generally became effective April 1, 1996.

For further inspection guidance, refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the NRC field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

O3.13 Posting and Labeling. The inspector should determine whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. Section 20.1903 provides exceptions to posting caution signs. When applicable, the inspector should also randomly examine signals and alarms to determine operability and audibility at occupied locations, per 10 CFR 36.23(b). The inspector should also randomly observe labeling on packages or other containers, to determine that proper date (such as isotope, quantity, and date of measurement) are recorded.

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. High-radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high-radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should

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be controlled in accordance with licensee procedures and consistent with the licensee's ALARA program.

The inspector should also examine locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

- 03.14 <u>Generic Communications of Information</u>. Through discussions with licensee management and the RSO, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, <u>NMSS Licensee Newsletter</u>, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. Also verify that the licensee has taken appropriate action in response to these NRC communications, when a response is required.
- 03.15 <u>Notifications and Reports</u>. The inspector should determine the licensee's compliance for notifications and reports to the Commission. The licensee may be required to make notifications after loss or theft of material, overexposures, incidents, high-radiation levels, safety-related equipment failure, etc. Additionally, some licensees are required to make annual reports to NRC.

Through discussions with licensee personnel, and by a review of representative records, the inspector should verify that notifications and/or reports were appropriately submitted to NRC.

- 03.16 <u>Special License Conditions</u>. Some licenses will contain special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions will state an exemption to a particular NRC requirement.
- 03.17 <u>Independent and Confirmatory Measurements</u>. The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility. Measurements of dose rates at the boundaries of the restricted areas should be performed at the surfaces of the most accessible planes. Examples of measurements that may be performed include area radiation surveys, soil samples, leak tests, water samples, etc. These measurements should be taken in licensed material use areas, storage areas, effluent release points, etc. Confirmatory measurements are those whereby the inspector compares his/her measurements with those of the licensee's. Independent measurements are those performed by the inspector independently of the licensee's measurements. To perform the independent or confirmatory measurement, use NRC radiation detection equipment that is calibrated at least annually.
- 03.18 Exit Meeting. When the inspection is over, there should be an exit meeting with the most senior licensee representative present at the facility. If a senior management representative is unavailable for the exit meeting, the inspector may hold a preliminary exit meeting with appropriate staff on site. However, there must be a formal exit meeting with a senior management representative (and the licensee's RSO, if not present at the preliminary exit meeting) as soon as practical after the inspection. This meeting will usually be performed by telephone conference call.

During the exit meeting, the licensee representatives should be made aware of the preliminary inspection findings, including any negative PEFs, apparent violations of regulatory requirements, safety-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations. Significant safety concerns must receive immediate attention from the licensee.

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If safety concerns or violations of significant regulatory requirements are identified that affect safe operation of a licensee facility, prompt corrective action must be initiated by the licensee. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated. If disagreement exists between the inspector and the licensee as to the magnitude of the concern relative to continued safe operation of the facility, regional management should be notified immediately.

Although deficiencies identified in some areas (e.g., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection report or Notice of Violation.

03.19 <u>Post-Inspection Actions</u>. Regional office policy will dictate with whom the inspector will review his or her inspection findings (e.g., the inspector's supervisor), following the guidance in IMC 2800, "Materials Inspection Program." The inspector should discuss the findings in the detail that is commensurate with the scope of the licensee's program. Violations, items of concern (e.g., negative PEFs), and unresolved items should be discussed in sufficient depth for management to make appropriate decisions regarding enforcement actions, referral to other State and Federal agencies, and decisions on the scheduling of future inspections of the licensee's facility.

The inspector should also discuss inspection findings with licensing staff. This information exchange can be particularly useful if the licensee is having its license renewed or has recently submitted a license amendment request. The inspector should inform licensing staff about how the licensee has addressed (or failed to address) special license amendments or recent licensing actions. Licensing information requested by the licensee should also be discussed with the licensing staff.

Inspectors should be aware that NRC has entered into several MOUs, with other Federal agencies, that outline agreements on items such as exchange of information and evidence in criminal proceedings. The inspector should ensure that the exchange of information relevant to inspection activities is made in accordance with the appropriate MOU.

The inspector may report the results of inspections to the licensee either by issuing an NRC Form 591 or a regional office letter to the licensee, following the guidance in IMC 2800. The inspector must also ensure that the findings are documented in the inspection record and/or inspection report, in sufficient detail for the reader to determine what requirement was violated, how it was violated, who violated the requirement, and when it was violated. The inspection record should not be used as merely a checklist to note areas reviewed. It should be used to describe what procedures or activities were observed and/or demonstrated by the licensee during the inspection, and any items of concern identified that were not cited as a violation of regulatory requirements.

Inspectors may complete the inspection record either by hand or electronically. If the inspector is documenting the inspection record in electronic format, the sub-items under major sections that are not applicable or not reviewed <u>may</u> be deleted. However, the heading itself (e.g., "Radioactive Waste Management," or "Transportation") should remain in the inspection record, and the inspector should enter appropriate remarks about why the section is not applicable or not reviewed.

For further inspection guidance, refer to Section 07.04 of IMC 2800.

87112-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in Section 2800-11 of IMC 2800. These documents are to be used as guidelines

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for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

Specific references to regulatory requirements can be located in the "Irradiator Inspection References" appendix. Appendix B, following this IP.

END

Appendices:

- Α.
- "Irradiator Inspection Record" "Irradiator Inspection References" В.

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